DEPARTMENT OF HEALTH AND HUMAN SERVICES

28 OCT 1996

Our Reference No. 95-0041 and 95-0087

Mr. Michael A. Trapani
Cytogen Corporation
600 College Road East
Princeton, NJ 08540

Dear Mr. Trapani:

Your biologics license application for Capromab Pendetide is approved effective this date. Cytogen Corporation, Princeton, New Jersey is hereby authorized to manufacture and ship for sale, barter, or exchange in interstate and foreign commerce Capromab Pendetide under Department of Health and Human Services Biologics License No. 1164.

Capromab Pendetide is indicated for the preparation of Indium In 111 Capromab Pendetide to be used as a diagnostic imaging agent in newly diagnosed patients with biopsy-proven prostate cancer, thought to be clinically localized after standard diagnostic evaluation, who are at high risk for pelvic lymph node metastases, and in post-prostatectomy patients with a rising PSA and a negative or equivocal standard metastatic evaluation in whom there is a high clinical suspicion of occult metastatic disease.

In accordance with approved labeling, your product will bear the tradename ProstaScint, and will be marketed as a single dose kit containing a 1 mL vial of Capromab Pendetide solution and a 1 mL vial of sodium acetate buffer solution.

You are not currently required to submit samples of future lots of Capromab Pendetide to the Center for Biologics Evaluation and Research (CBER) for release by the Director, CBER, under 21 CFR 610.2. FDA will continue to monitor compliance with 21 CFR 610.1 requiring assay and release of only those lots that meet release specifications.

The dating period for this product shall be 24 months from the date of manufacture when stored at 2-8° C. The date of manufacture shall be defined as the date of final sterile filtration of the formulated product. The bulk Capromab antibody may be stored for up to 36 months at 2-8°C or -70°C. Results of ongoing stability studies should be submitted throughout the dating period as they become available including the results of stability studies from the first three production lots.

We acknowledge your written commitment of October 25, 1996 to submit a galley proof of the package insert for review and approval prior to implementation.

Any changes in the manufacture, packaging or labeling of the product or in the manufacturing facilities will require the submission of information to your biologics license application for our review and written approval consistent with 21 CFR 601.12.

It is requested that adverse experience reports be submitted in accordance with the adverse experience reporting requirements for licensed biological products (21 CFR 600.80) and that distribution reports be submitted as described (21 CFR 600.81). These requirements became effective on December 27, 1994. All adverse experience reports should be prominently identified according to 21 CFR 600.80 and be submitted to the Center for Biologics Evaluation and Research, HFM-210, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448.

Please submit three copies of all final printed labeling at the time of use and include part II of the label transmittal form (FDA Form 2567) with completed implementation information. In addition, you may wish to submit draft copies of the proposed introductory advertising and promotional labeling with an FDA Form 2567 to the Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Staff, HFM-202, 1401 Rockville Pike, Rockville, MD 20852-1448. Final printed advertising and promotional labeling should be submitted at the time of initial dissemination, accompanied by an FDA Form 2567. All promotional claims must be consistent with and not contrary to approved labeling. No comparative promotional claim or claim of superiority over other similar products should be made unless data to support such claims are submitted to and approved by the Center for Biologics Evaluation and Research.

Sincerely yours,

Jay P. Siegel, M.D., FACP
Director
Office of Therapeutics
Research and Review
Center for Biologics
Evaluation and Research

Jerome A. Donlon, M.D., Ph.D.
Director
Office of Establishment Licensing
and Product Surveillance
Center for Biologics
Evaluation and Research